Cemented versus hydroxyapatite fixation of the femoral component of the Freeman-Samuelson total knee replacement

A RADIOSTEREOMETRIC ANALYSIS

J. Uvehammer, J. Kärrholm, L. Carlsson

From Sahlgrenska University Hospital, Göteborg, Sweden

We have carried out a radiostereometric study of 50 patients (54 knees) with osteoarthritis of the knee who were randomly allocated to receive a cemented or a hydroxyapatite-coated femoral component for total knee replacement. The patients were also stratified to receive one of three types of articulating surface (standard, rotating platform, Freeman-Samuelson (FS)1000) all based on the Freeman-Samuelson design. The tibial components were cemented in all cases. Radiostereometry was performed post-operatively and at 3, 12 and 24 months. The analysis was restricted to rotation of the femoral component over time.

After two years, rotation of the femoral components in the transverse, longitudinal and sagittal planes did not differ between the cemented and the hydroxyapatite-coated implants (p = 0.2 to 0.9).

In total knee replacements with a rotating platform, the femoral component tended to tilt more posteriorly than in the other two designs, regardless of the choice of fixation (cemented or hydroxyapatite-coated, p = 0.04). The standard version of the femoral component, whether cemented or hydroxyapatite-coated, rotated more into valgus than was observed with the rotating-platform and FS1000 designs (p = 0.005). The increased constraint provided by the FS1000 component did not appear to have any adverse effect on fixation of the femoral component.

The choice of whether to use cemented or uncemented fixation of a total knee replacement (TKR) has been debated. Some recently-published studies have supported the use of uncemented, hydroxyapatite (HA)-coated TKRs based on reports of good long-term results.1,2 König et al1 concluded that a hybrid TKR, with uncemented femoral and cemented tibial components, gave results comparable with those of fully-cemented implants. These investigations were prospective, but not stratified. There have been some randomised radiostereometric (RSA) studies which have compared cemented tibial components with HA-coated fixation,4-6 but we are not aware of a study which has examined the fixation of the femoral component.

We have used RSA to measure the migration of three variations of the Freeman-Samuelson knee replacement (Finsbury Orthopaedics Ltd, Leatherhead, United Kingdom) each with the femoral component cemented or uncemented (HA-coated fixation). We are not aware of a study which has examined the fixation of the femoral component.

Patients and Methods
We recruited 50 patients (40 women, 10 men) with a mean age of 72 years (51 to 82), who had non-inflammatory arthritis of Ahlbäck7 grade 2 to 5, affecting 54 knees. Using a system of sealed envelopes opened by one of five surgeons (JU, LC, JK, and two who are not authors) before the operation, the patients were randomised into one of the six treatment options. The uncemented femoral components had been coated on their non-articulating surface with HA to a thickness of 75 µm (± 20). Refobacin-Palacos R bone cement (Biomet Orthopaedics Inc., Warsaw, Indiana) prepared by vacuum mixing was used for the cemented femoral components.
All the tibial components were cemented using the same cement as on the femoral side. The standard and rotating-platform tibial components had identical articulating geometry. The moveable platform rotated around a central peg, whereas the fixed inserts (standard and FS1000) had a snap-fit into the metal tibial tray. All the femoral components were manufactured with an 80 mm stem and were only available in one size (size 2/medium). This made the series more homogeneous regarding biomechanical factors, but excluded selection of patients with larger or smaller knees.

The design of the femoral components for articulation against the standard and the rotating-platform implants was identical, conforming to the principle of a ‘roller-in-trough’. In the FS1000 TKR the medial femoral condyle had been modified and was represented by a portion of a sphere, but on the lateral side continued in the form of the roller-in-trough design. Compared with standard and rotating TKRs, the FS1000 implant had an increased contact area medially and also a higher anterior flange on the medial side of the tibial insert, creating more constraint. The design was intended to allow some anteroposterior translations of the lateral, but not of the medial, femoral condyle.

To make RSA evaluation possible the manufacturer (Finsbury Orthopaedics Ltd) had prepared the femoral components with four small titanium towers, each supplied with one tantalum marker. The tip of the stem had one of these towers secured as a press fit. One tower was located on the proximolateral aspect of the anterior flange and the other two posteriorly on the medial and lateral condyles, respectively (Figs 1 to 3).

Before operation the patients were randomised to receive a cemented (31 knees) or an uncemented (23 knees) implant and also to one of the three designs. After randomisation there were 19 standard components (12 cemented, 7 HA), 16 with a rotating platform (8 cemented, 8 HA) and 19 FS1000 (11 cemented, 8 HA). The procedure was performed with instruments supplied by the manufacturer. All the operations were carried out at one centre by one of five surgeons with many years’ experience of implantation of the Freeman-Samuelson knee prosthesis. Bilateral TKRs were undertaken in four patients, but the same design was not used in both knees.

Patients were excluded from the study if the size 2 femoral component was not appropriate. As a consequence of this, other limitations in the study protocol and a general decrease in operating activity caused by temporary economic restrictions, patient recruitment lasted for about two years.

The posterior cruciate ligament was partially or totally resected in all cases. For the subsequent RSA examinations, eight to nine tantalum balls, approximately 0.8 mm in diameter were inserted into the distal femur using a dedicated tantalum ball injector. This procedure was performed before implantation of the components. In 44 knees a patellar component was inserted.

**Radiostereometry.** RSA examinations were carried out three to six days after the operation. Subsequent investigations were undertaken after 3, 12 and 24 months. The biplanar, digital measurement technique and the UmRSA 3.2 software (RSA Biomedical Innovations, Umeå, Sweden) were used. In our study we chose to restrict our evaluation to rotation around the transverse (anterior (+)/posterior (+) tilt), longitudinal (internal (+)/external (-) rotation) and sagittal (varus (+)/valgus (-) tilt) axes (Fig. 4).
Five patients (six knees) had incomplete follow-up at two years. Three (1 HA/standard implant, 1 cemented/rotating platform, 1 cemented/FS1000) died for reasons unrelated to the surgical procedure. One patient with bilateral TKR (1 cemented/rotating platform, 1 HA/FS1000), suffered from dementia and could not participate in the study. RSA was not possible in one patient (cemented/FS1000) because of poor tantalum marking. Thus, 48 knees (18 standard (12 cemented, 6 HA), 14 rotating platforms (6 cemented, 8 HA), and 16 FS1000 (9 cemented, 7 HA)) in 45 patients were followed up at one and two years after operation by RSA, conventional radiography and with a clinical examination. At the follow-up at two years complete RSA results for the migration of the femoral component relative to the femur were available for 38 knees (12 standard (9 cemented, 3 HA), 13 rotating platforms (6 cemented, 7 HA) and 13 FS1000 (6 cemented, 7 HA)). The remaining knees had to be excluded since too few tantalum markers could be visualised in the femoral component. The reason for this was the width and length of the femoral stem and the high anterior femoral flange which obscured two or more of the four femoral markers on either view.

Conventional radiography and clinical evaluation. The hip-knee-ankle angle (HKA)\textsuperscript{14} and the Hospital for Special Surgery (HSS) knee score\textsuperscript{15} were recorded pre-operatively and at the follow-up at two years.

Statistical analysis. The Mann-Whitney U and Kruskal-Wallis tests were used for the analysis. Median values and ranges were reported. If the choice of fixation and design of the implant were considered as independent factors, our study could detect differences in migration caused by fixation (i.e. cemented or HA-coated femoral components) with a probability of 80% if they exceeded 1.0° and differences caused by design if they exceeded 1.5°, depending on the direction of the rotation. The level of statistical significance was set at \( p \leq 0.05 \).
Results

Radiostereometry - fixation (Table I). At two years the median posterior (+) or anterior (-) tilt for the cemented and HA-coated femoral components relative to the femoral bone were close to 0˚ (cemented, 0.06˚ (-0.86˚ to +1.57˚); HA-coated 0.17˚ (-1.65˚ to +1.78˚), p = 0.9). The cemented femoral components showed small internal (+) rotations during this time (0.15˚ (-1.42˚ to +2.13˚) and the HA-coated external (-) rotation (-0.14˚ (-4.32˚ to +1.00˚) but without any significant difference (p = 0.2). Minimum varus (+) or valgus (-) tilt was observed (cemented, -0.10˚ (-1.52˚ to +1.45˚); HA-coated, 0.16˚ (-2.86˚ to +2.57˚), p = 0.2).

Radiostereometry - design (Table II). At two years the results for a rotating platform showed that it tilted more posteriorly (0.25˚ (-0.71˚ to +1.78˚) than did the FS 1000 (0.15˚ (-1.28˚ to +1.31˚) p = 0.04). The standard version also differed from the rotating-platform design and showed anterior tilt (-0.16˚ (-1.65˚ to +1.35˚), rotating platform vs standard p = 0.04). No differences could be detected between the standard and FS1000 implants (p = 0.2).

The internal (+)/external (-) rotation did not differ between the three groups (standard, -0.15˚ (-4.32˚ to +0.99˚), rotating platform, 0.24˚ (-0.76˚ to +2.13˚); FS1000, 0.07˚ (-1.42˚ to +1.32˚), p = 0.4 to 0.8).

At follow-up at two years the standard implants had rotation into valgus of -0.25˚ (-2.86˚ to +0.16˚), whereas the other two versions showed a minimal varus rotation (rotating platform, +0.09˚ (-1.40˚ to +0.67˚); FS1000, +0.26˚ (-0.35˚ to +2.57˚) (p = 0.005). The varus/valgus rotation did not differ between the rotating platform and the FS1000 designs (p = 0.9).

Clinical results. At the follow-up at two years the median HSS score for the cemented and uncemented groups was 92 (66 to 98) and 94 (70 to 98) respectively; p = 0.4). The HSS scores did not differ in the three versions of the design (p = 0.7 to 0.9).

Discussion

RSA has evolved as an important tool for obtaining a preliminary evaluation of new implants or surgical methods and because of a high resolution, prediction of outcome can also be made based on a limited patient population. This method has been applied many times in orthopaedic surgery.16 Clinical scores are more difficult to interpret, because of several confounders partly related to diseases of other joints and the general health of the patient. In addition, symptoms caused by failing implants will often appear

---

Table I. Median rotation (range) in degrees, (transverse, longitudinal, sagittal) at two years of the femoral components (cemented, hydroxyapatite (HA)-coated) of the Freeman-Samuelson total knee replacement

<table>
<thead>
<tr>
<th>Rotation</th>
<th>Cemented</th>
<th>HA-coated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior (+)/posterior (+) tilt</td>
<td>+0.06 (-0.86 to 1.57)</td>
<td>+0.17 (-1.65 to 1.78)</td>
</tr>
<tr>
<td>Internal (+)/external (-) rotation</td>
<td>+0.15 (-1.42 to 2.13)</td>
<td>-0.14 (-4.32 to 1.00)</td>
</tr>
<tr>
<td>Varus (+)/valgus (-) tilt</td>
<td>-0.10 (-1.52 to 1.45)</td>
<td>+0.16 (-2.86 to 2.57)</td>
</tr>
</tbody>
</table>

Table II. Median rotation (range) in degrees (transverse, longitudinal and sagittal) at two years of the femoral components (cemented, hydroxyapatite-coated) in the three different designs of the Freeman-Samuelson total knee replacement

<table>
<thead>
<tr>
<th>Rotation</th>
<th>Standard</th>
<th>Rotating platform</th>
<th>FS1000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior (+)/posterior (+) tilt</td>
<td>-0.16 (-1.65 to 1.35)</td>
<td>+0.25 (-0.71 to 1.78)</td>
<td>+0.15 (-1.28 to 1.31)</td>
</tr>
<tr>
<td>Internal (+)/external (-) rotation</td>
<td>-0.15 (-4.32 to 0.99)</td>
<td>+0.24 (.076 to 2.13)</td>
<td>+0.07 (-1.42 to 1.32)</td>
</tr>
<tr>
<td>Varus (+)/valgus (-) tilt</td>
<td>-0.25 (-2.86 to 0.16)</td>
<td>+0.09 (-1.40 to 0.67)</td>
<td>+0.26 (-0.35 to 2.57)</td>
</tr>
</tbody>
</table>
after some delay which sometimes may extend over several years.

A weakness in our study was that relatively few patients were included. There were also some RSA examinations which were unsuitable for analysis, mainly due to difficulties in the visualisation of the tantalum markers. These technical difficulties could possibly explain why RSA studies of migration of femoral components have not been performed earlier. However, the RSA technique has a precision about 20 times better than that of conventional methods and those remaining cases in which complete RSA analysis was possible were sufficient in number to arrive at relevant conclusions with reasonable certainty according to our power analysis.

At two years we found no differences when the fixation of the cemented and uncemented, HA-coated, femoral components were compared. Several authors have reported good results with uncemented, HA-coated knee replacements with a follow-up of at least seven years, including the Freeman-Samuelson design. Also, hybrid TKRs with an uncemented HA-coated femoral component and a cemented tibial component have produced encouraging results. Some authors have recommended HA coating for uncemented implants since it gives better results than the use of porous coatings. In a recently published RSA evaluation, Carlson et al found better fixation of cemented compared with uncemented (porous-coated or HA-coated) tibial components, which supports the use of cement for fixation of tibial components in TKR.

In another RSA study, Nilsson et al did not find any difference between cemented and HA-coated tibial implants indicating that observations from one study could not be generalised.

Our second hypothesis, that the more constrained configuration in the FS1000 design would result in more micromovement of the femoral component, was not confirmed. On the contrary, the results showed that this implant was more stable compared with the other two designs. The femoral component of the FS1000 TKR did not have a tendency to posterior tilting, as was found in the femoral components articulated against a rotating platform, or a rotation into valgus which was seen in the standard implants. Previously, we have studied fixation of the tibial component in these three different versions of the Freeman-Samuelson TKR. The fixation to the proximal tibia of the metal-backed, cemented implant did not differ in all the configurations. This outcome was in accordance with the results obtained when migration of the tibial component in the AMK (DePuy, Johnson & Johnson, Warsaw, Indiana) knee replacement was examined. These investigations showed that the degree of constraint of the tibial insert had no influence on the micromovement of the tibial component. However, when kinematic RSA studies of the AMK implant were performed, differences could be seen in all three designs (flat, concave and posteriorly stabilised).

In a previous dynamic RSA study, the joint kinematics of the three versions of the Freeman-Samuelson design used in this study showed significant differences in the pattern of joint movement, which could be related in part to the design of the articulating surfaces. Thus, two studies of variations in one basic implant design showed that these variations had an influence on knee kinematics, but not on the migration of the tibial component. According to our knowledge this is the first time that RSA has been used to study any corresponding influence on the femoral component. Interestingly, and contrary to the findings on the tibial side, the design of the articulating surfaces did influence the fixation of the femoral component.

This project was financially sponsored by the Felix Neubergh Research Foundation, the Gothenburg Medical Society, the Swedish Medical Research Council, Finsbury Orthopaedics (UK) and the Centre for Research and Development, Skaraborg Hospital. The original implant with medial rotational characteristics referred to as the FS1000 in this report is now known as the MRK (Finsbury Orthopaedics). No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


